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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,585	09/19/2001	Ali I. Fattom	018861-0216	8124
22428	7590	12/04/2003	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			DUFFY, PATRICIA ANN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/955,585	Applicant(s) FATTOM ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Prior to the outset of the restriction requirement it is noted that claim 1 recites an improper Markush Group. M.P.E.P. 803.02 states that: "Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 11, 12 and 14-19 drawn to immunization with 1(a) glycoconjugates of both type 5 and type 8 polysaccharide antigens of *Staphylococcus aureus*, classified in class 424, subclass 197.11.
- II. Claims 1, 4, 5, 11, 12 and 14-19, drawn to immunization with 1(b) glycoconjugates of a negatively charged Staphylococci *polysaccharide antigen* containing no O-acetyl groups, classified in class 424, subclass 197.11.

- III. Claims 1, 7 and 13-19, drawn to immunization with 1(c) glycoconjugates of a Staphylococcal *glycopeptide antigen* that contains amino acids and a N-acetylated hexosamine in an alpha configuration and no O-acetyl groups and that contains no hexose, classified in class 424, subclass 197.11.
- IV. Claims 1, 6, 11, 12 and 14-19, drawn to immunization with 1 (d) glycoconjugates of an acidic Staphylococcal *polysaccharide antigen* that is obtained from an isolate of *S. epidermidis*, classified in class 424, subclass 197.11.
- V. Claims 1, 8, 11, and 14-19, drawn to immunization with 1(e) glycoconjugates of an *E. faecalis* antigen that comprises 2-acetamido-2-deoxy-glucose and rhamnose in a 1:2 molar ratio, classified in class 424, subclass 197.11.
- VI. Claims 1, 9, 11 and 14-19, drawn to immunization with 1(f) glycoconjugates of an *E. faecalis* antigen that comprises a trisaccharide repeat comprising a 6-deoxy sugar, classified in class 424, subclass 197.11.
- VII. Claims 1, 10, 11 and 14-19, drawn to immunization with 1(g) glycoconjugates an *E. faecalis* antigen that comprises 2-acetamido-2-deoxy-galactose and galactose in a 2:1 molar ratio, classified in class 424, subclass 197.11.
- VIII. Claims 1, 12 and 14-19, drawn to immunization with 1(h) glycoconjugate of an antigen that reacts with antibodies to ATCC 202016 , classified in class 424, subclass 197.11.

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IX. Claims 1, 12, and 14-19, drawn to immunization with 1(i) glycoconjugate of an antigen that reacts with antibodies to ATCC 202017, classified in class 424, subclass 197.11.

The inventions are distinct, each from the other because of the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Related Inventions" in M.P.E.P.

806.05 for "inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct

inventions for the following reasons:

Groups I-IX are directed to the administration of products that are distinct physically, structurally, and functionally, and are therefore patentably distinct, each group from the other, and are not required one for the other. Each group comprises separate and distinct glycoconjugates, glycopeptide or bacterial surface antigens which do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555. The examiner can normally be reached on M-F 10:30pm-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patricia A. Duffy
Patricia A. Duffy
Primary Examiner
Art Unit 1645